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(54) Title: TABLETS COATED WITH LOCUST BEAN GUM, GUAR GUM OR CARRAGEENAN GUM

(57) Abstract: A hydrocolloid coated tablet, a hydrocolloid tablet coating, a method to prepare hydrocolloid compositions useful to coat tablets, a method of treating patients using tablets, an article of manufacture, comprising aspirin, ibuprofen, naproxen sodium, acetaminophen, celecoxib, oxaprozin, sildenafil citrate, alendronate sodium, combinations thereof and the like, and optionally other combinations of active drugs and optionally one or more of an analgesic and more or more of antihistamine, decongestant, antitussive or expectorant, mixtures thereof and the like. More particularly, this invention relates to a tablet coated with a hydrocolloid(s) selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan, mixtures thereof and the like.

TABLETS COATED WITH LOCUST BEAN GUM, GUAR GUM OR CARRAGEENAN GUM

5 This invention relates generally to a hydrocolloid coated tablet, to a hydrocolloid tablet coating, to a method to prepare hydrocolloid compositions useful to coat such tablet(s), a method for treating patients using such tablets and to an article of manufacture comprising such a tablet(s). More particularly, this invention relates to a tablet comprising one or more active ingredient(s) including but not limited to
10 aspirin, ibuprofen, naproxen sodium, acetaminophen, celecoxib, oxaprozin, sildenafil citrate, alendronate sodium, mixtures thereof and optimally an analgesic in combination with one or more of an antihistamine, antitussive, decongestant, expectorant and mixtures thereof, or the like, combinations thereof, and with other medications and the like, coated with a hydrocolloid(s) selected from the group
15 consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum, mixtures thereof and the like.

BACKGROUND OF THE INVENTION

20 Tablets are used typically to deliver a pharmacologically effective amount of a therapeutic drug to humans and animals so as to provide medicinal benefit to the human or animal. Typically such therapeutically effective drugs include (but are not limited to) a drug or a suitable mixture of drug(s) that possess and produce desirable physiological effects after effective consumption by the human or
25 animal. Such drugs include but are not limited to a medicine(s). Such consumption methods include oral (swallowing) or rectal, for example by the human or animal so that the drug is made effectively available internally to the human or animal.

30 HPMC is a useful coating for tablets. However, even with present tablet coating compositions which include HPMC, the industry continues to desire a

product which provides enhanced tablet coating. The process of preparing and method of administering an improved and enhanced tablet coating continues to be of interest.

5

OBJECTS OF THE INVENTION

It is an object of this invention to provide a tablet coating comprising a hydrocolloid selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum, and mixtures thereof preferably with
10 a low weight gain attribute of the coating on a coated tablet.

It is another object of this invention to provide a tablet (effective for human oral consumption) effectively coated with a hydrocolloid selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum,
15 and mixtures thereof which has a low weight coating.

It is an object of this invention to provide a process of effectively coating an tablet using a hydrocolloid selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum and mixtures thereof.
20

It is a further object of this invention to provide a tablet with active ingredients (illustratively analgesics and antipyretics and anti-inflammatories such as aspirin, acetaminophen, ibuprofen, naproxen sodium, celecoxib, oxaprozin, sildenafil citrate, alendronate sodium, and optionally their combination products with
25 antihistamines, antitussives, decongestants and expectorants) coated with a hydrocolloid selected from the group consisting of locust bean gum, (Galactomannans), guar gum, carrageenan and mixtures thereof.

The above and various other objects are met in this invention which is
30 more particularly described hereinafter without limitation.

BRIEF DESCRIPTION OF THE INVENTION

This invention comprises a tablet coating comprising a hydrocolloid selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum, mixtures thereof and the like. In another embodiment this invention comprises a process for preparing such a suitable hydrocolloid tablet coating composition. In yet another embodiment this invention comprises a process for effectively administering a tablet coated in accordance with this invention to a human or animal patient. In another embodiment, this invention comprises the effective administration of a hydrocolloid coated tablet of this invention may be by oral or rectal delivery to a human or animal and typically includes a medicine as a drug in a therapeutically effective amount whereby the drug is made effectively available to the patient for consumption. Other embodiments follow in the specification.

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DETAILED DESCRIPTION OF THE INVENTION

Hydrocolloids useful in this invention are selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan, mixtures thereof and the like.

20

Active ingredients which may be coated in this invention include illustratively without limit pharmaceutical active ingredients such as celecoxib, oxaprozin, sildenafil citrate, alendronate sodium, and optimally an analgesic in combination with one or more of an antihistamine, antitussive, decongestant, expectorant, mixture thereof and the like, and over the counter (OTC) drugs such as those typically delivered in a suitable tablet dosage form including for example, medicines for humans and animals taken as for example by ingestion. Illustrative examples include but are not limited to analgesics and antipyretic and anti-inflammatory(s) such as aspirin, acetaminophen, ibuprofen, naproxen sodium B;

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phacetine, steroids including anti-inflammatory steroids, enzymes, proteins, antibiotics, mixtures thereof and the like.

Various decongestants, antitussives, expectorants, antihistamines may
5 be employed with any one or a combination of the active ingredients disclosed herein if desired. Such decongestants, antitussives, expectorants and antihistamines are illustrated below and are not limited:

Decongestants (Pseudoephedrine, Phenylpropanolamine, Ephedrine,
10 Epinephrine, Phenylephrine, Naphazoline, Xylometazoline, Oxymetazoline);
Antitussives (Codeine, Dextromethorphan, Diphenhydramine, Benzonatate,
Chlophedianol, Noscapine, Carbetapentane Citrate); Expectorants (Guaifenesin,
Iodine Products, Terpinhydrate, Ammonium Chloride, Beechwood Creosote,
Potassium, Guaiacolsulfonate, Syrup Ipecac); and Antihistamines (Pheniramine,
15 Thonzylamine, Phenyltoloxamine, Doxylamine, Diphenhydramine, Carbinoxamine,
Clemastine, Tripelemamine, Pyrilamine Maleate, Chlorpheniramine,
Dexchlorpheniramine, Brompheniramine, Triprolidine, Promethazine, Trimeprazine,
Methdilazine, Cylcoheptadine, Azatadine, Diphenylpyraline, Phenindamine),
mixtures thereof and the like.

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Neither the tablet shape nor the tablet size of tablets suitable for this
invention are critical. Shapes may be round or oval, caplet or capsule shaped,
however, other shapes may be employed if desired. Preferred tablets are medicinal
tablets for humans or animals. The tablets include but are not limited to tablets of an
25 convenient composition which may or may not contain any pharmaceutically effective
drug, vitamin, or nutrient or drugs suitable for human and/or animal consumption.
Ibuprofen and acetaminophen are preferred actives herein.

Colors and pigments may be employed in coatings of this invention
30 and include those, without limit, of Jeffries, U.S. Patent No. 3,149,040; Butler et al.

U.S. Patent No. 3,297,535; and Colorcon, U.S. Patent No. 3,981,984. All three of these U.S. Patents are incorporated herein by reference in their entirety.

As employed herein, the term "tablet" includes without limit, tablet,
5 caplet, particle, micronized particle, particulate, pellet, pill, core, powder, granule, granulated, small mass, seed, speck, sphere, crystal, bead, agglomerate, and mixtures thereof and the like. Typically the tablet will be in a form sufficient stable physically and chemically to be effectively coated in a system which involves some movement of the tablet, as for example in a fluidized bed, such as in a fluidized bed dryer or a
10 side vented coating pan, combinations thereof and the like. Virtually any tablet, placebo, the latter typically lactose or sugar or mixtures thereof and the like is acceptable herein as a tablet to be coated in the practice of this invention. The amount of coating employed herein is preferably an effective adherent amount. One or more layers of coating may be employed. Continuous or nearly continuous or
15 semicontinuous coating may be employed if desired.

In practicing this invention, a tablet(s) to be coated herein may be preferably inserted into either a side vented coating pan or a fluid bed coating apparatus. If desired, the candidate gum or mixtures thereof may be mixed into
20 aqueous solution using a standard laboratory mixer (high shear). To facilitate getting into solution heat may or may not be used. Plasticizer or surfactant material may or may not be incorporated into the coating solution preparation. The coating solution is then preferably applied as for example, by spraying (pumping systems may vary from peristaltic, to gear pumps, to positive displacement pumps, etc.) onto the tablet(s) to
25 be coated at conventional equipment settings (air flow, spray rates, process temperatures, nozzle selection, air volumes, etc.) Those of skill in the art will be able to practice this invention after reading this specification and utilizing their skill and knowledge in the art.

30 Preferably the percentage solids in the hydrocolloid coating composition of this invention is generally in the range from about 0.05% to about 4%

solids, while a preferred range is about 0.1% to about 2% solids and a more preferred range is about 0.5% to about 1.5% solids. Those of skill in the art will recognize that greater as well as lesser concentrations of solids in the hydrocolloid coating compositions of this invention may be employed depending on a number of factors
5 including the selection of hydrocolloid or hydrocolloids, tablet or tablets to be coated.

During the coating process of this invention, illustratively the amount of weight gain of a tablet is generally in the range from about 0.05% to about 3%, more preferably in the range from about 0.10% to about 1% and most preferably
10 from about 0.2% to about 0.5% although those of skill in the art will recognize that greater or lesser weight gains may be employed if desired as long as an effective weight gain is employed. The temperatures and operating conditions of the process of this invention may be varied as desired to produce a quality product of this invention.

15

The amount of coating weight on the coated tablet is very important in that the lower weight gain is highly desirable as such aids in more cost effective processing and preparation of the tablets – yet a highly effective tablet coating is provided.

20

Any acceptable coating application system may be employed in this invention which has the capability to apply a gum coating composition of this invention to a suitable tablet. For example a plain fluid bed system (one with or without a Wurster insert) including a fluid bed spray tower may be employed. Air
25 suspension coating systems useful herein include but are not limited to those described in Ullman's Encyclopedia of Industrial Chemicals Volume A16 pages 583-0584 (1990) includes a description of the Wurster process and is incorporated herein by reference in its entirety.

Side vented coating pan systems, spray drying systems, continuous coating pans, conventional coating pans are useful in the practice of this invention as is a fluid bed dryer such as those with or without a Wurster type insert.

5 Particularly useful self-contained side vented coating systems in this invention are available under the Accela Cota brand sold by Thomas Engineering Incorporated, 575 West Central Road, Hoffman Estates, Illinois 60195-0198, U.S.A. Various size pans may be employed herein. Those of skill in the art will recognize that adjustment will probably be needed to tune the dryer and application system to
10 the individual gum and tablet selected for the practice of this invention.

EXAMPLES

Examples 1- 3, hereinafter following, are provided to illustrate the
15 preparation of acceptable coated tablets in accordance with this invention and are provided by way of illustration and are not intended to limit the invention in any way. All percents and any parts are by weight unless otherwise indicated. Various application systems including fluidized feed systems and pan side vented coating systems are illustrated without limitation.

20 An evaluation of locust bean gum, carrageenan gum and guar gum as coatings for tablets (active drug ingredients) was successfully done in Examples 1-3 to observe visual appearance after being coated on actives as regards coating capability. Overall functionality and appearance was observed.

25 PROCEDURE:

In Examples 1-3 (following) a 15" Accela-Cota coating pan with a peristaltic pump and spraying apparatus was employed to prepare acceptable hydrocolloid coated
30 active (medicinal) drugs.

Charge: tablets with actives (aspirin, acetaminophen, sodium naproxen, ibuprofen, aspirin with caffeine, buffered aspirin, multi-vitamins and combinations). These actives were added to uncoated 3/8" concave placebos where final charge was 1.9 kg.

5 Example 1:

99.25%	1488.75 grams	Deionized Water (DI water)
0.75%	11.25 grams	Guar (TIC Gums, Inc.)

Guar gum was added to DI water and heated to 60°C. After dissolving, 525.7 grams
10 was sprayed (50°C) onto tablets of each of aspirin, acetaminophen, sodium naproxen, ibuprofen, aspirin with caffeine, buffered aspirin, and multi-vitamins and combinations to a 0.20% weight gain.

Example 2:

15 98.5%	1477.5 grams	Deionized Water (DI)
1.5%	22.5 grams	Carrageenan gum (TIC Gums)

Carrageenan gum was added to DI water and heated to 50°C. After dissolving, 298 grams was sprayed (50°C) onto tablets of aspirin, acetaminophen, sodium naproxen,
20 ibuprofen, aspirin with caffeine, buffered aspirin, and multi-vitamins and combinations to a 0.20% weight gain.

Example 3:

25 98.5%	1477.5 grams	Deionized Water
1.5%	22.5 grams	Locust Bean Gum (TIC Gums, Inc.)

Locust Bean gum was passed through a standard screen (USP 200 mesh) to remove/break up impurities/insoluble particles. Locust Bean gum was added to DI water, and initially heated to 70°C. After dissolving was complete, 298 grams were
30 sprayed (50°C) onto tablets to a 0.20% weight gain.

In Examples 1-3 above, acceptable coated tablets were prepared by using the gums of this invention as film coating onto tablets with actives.

Thus, it is apparent that there has been provided, in accordance with
5 the instant invention, tablets, tablet coating(s), a process, a method of use, a composition, and an article of manufacture that satisfies the object and advantages set forth herein above of hydrocolloid type coating applied to tablets with active (drug) ingredients. While the invention has been described with respect to examples and
10 embodiments thereof, it is understood that the invention is not limited thereto and many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description. Accordingly, it is intended to embrace all such alternatives, modifications and variations as fall within the spirit and broad scope of this invention.

WHAT IS CLAIMED IS:

1. A tablet coating comprising a hydrocolloid selected from the group
5 consisting of locust bean gum (Galactomannans), guar gum and carrageenan gum.
2. The tablet coating of Claim 1 wherein said hydrocolloid comprises carrageenan gum.
- 10 3. The tablet coating of Claim 1 wherein said hydrocolloid comprises guar gum.
4. The tablet coating of Claim 1 wherein said hydrocolloid comprises locust bean gum.
- 15 5. The tablet coating of Claim 1 wherein said hydrocolloid comprises a mixture, blend or combination of hydrocolloids selected from the group consisting of locust bean gum (Galactomannans), guar gum and carrageenan gum.
- 20 6. The tablet coating of Claims 1-5 wherein said gum is present in an amount in the range from about 0.05% to about 3% by weight of the total coated tablet.
- 25 7. The tablet coating of Claim 6 wherein said gum is present in an amount in the range from about 0.1% to about 1% by weight of the total coated tablet.
- 30 8. The tablet coating of Claim 7 wherein said gum is present in an amount in the range from about 0.2% to about 0.5% by weight of the total coated tablet.

9. A coated active drug having a coating composition therewith comprising a hydrocolloid selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum and mixtures thereof.

5 10. The coated drug of Claim 9 wherein said hydrocolloid comprises carrageenan gum.

11. The coated drug of Claim 9 wherein said hydrocolloid comprises guar gum.

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12. The coated drug of Claim 9 wherein said hydrocolloid comprises locust bean gum.

13. The coated drug of Claim 9 wherein said hydrocolloid comprises a mixture, blend or combination of hydrocolloids selected from the group consisting of locust bean gum, guar gum and carrageenan gum.

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14. The coated drug of Claims 9-13 wherein said gum is present in an amount in the range from about 0.05% to about 3% by weight of the total tablet.

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15. The coated drug of Claims 9-13 wherein said gum is present in an amount in the range from about 0.1% to about 1% of the total coated tablet.

16. The coated drug of Claims 9-13 wherein said gum is present in an amount in the range from about 0.2% to about 0.5% of the total coated tablet.

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17. The coated drug of Claim 10 wherein said drug comprises aspirin.

18. The coated drug of Claim 10 wherein said drug comprises ibuprofen.

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19. The coated drug of Claim 10 wherein said drug comprises acetaminophen.
20. The coated drug of Claim 10 wherein said drug comprises naproxen sodium.
21. The coated drug of Claim 10 wherein said drug comprises aspirin with caffeine.
22. The coated drug of Claim 10 wherein said drug comprises buffered aspirin.
23. The coated drug of Claim 10 wherein said drug comprises multi-vitamins and combinations.
24. The coated drug of Claim 10 wherein said drug comprises celecoxib.
25. The coated drug of Claim 10 wherein said drug comprises oxaprozin.
26. The coated drug of Claim 10 wherein said drug comprises sildenafil citrate.
27. The coated drug of Claim 10 wherein said drug comprises alendronate sodium.
28. The coated drug of Claim 10 which said drug comprises an analgesic and one or more of an antihistamine, decongestant, antitussive or expectorant or, a mixture(s) thereof.
29. The coated drug of Claim 11 wherein said drug comprises aspirin.

30. The coated drug of Claim 11 wherein said drug comprises ibuprofen.
31. The coated drug of Claim 11 wherein said drug comprises
5 acetaminophen.
32. The coated drug of Claim 11 wherein said drug comprises sodium
naproxen.
- 10 33. The coated drug of Claim 11 wherein said drug comprises aspirin with
caffeine.
34. The coated drug of Claim 11 wherein said drug comprises buffered
aspirin.
15
35. The coated drug of Claim 11 wherein said drug comprises multi-
vitamins and combinations.
36. The coated drug of Claim 11 which said drug comprises an analgesic
20 and one or more of an antihistamine, decongestant, antitussive or expectorant or a
mixture thereof.
37. The coated drug of Claim 11 wherein said drug comprises celecoxib.
- 25 38. The coated drug of Claim 11 wherein said drug comprises oxaprozin.
39. The coated drug of Claim 11 wherein said drug comprises sildenafil
citrate.
- 30 40. The coated drug of Claim 11 wherein said drug comprises alendronate
sodium.

41. The coated drug of Claim 12 wherein said drug comprises aspirin.
42. The coated drug of Claim 12 wherein said drug comprises ibuprofen.
- 5 43. The coated drug of Claim 12 wherein said drug comprises acetaminophen.
44. The coated drug of Claim 12 wherein said drug comprises sodium
10 naproxen.
45. The coated drug of Claim 12 wherein said drug comprises aspirin with caffeine.
- 15 46. The coated drug of Claim 12 wherein said drug comprises buffered aspirin.
47. The coated drug of Claim 12 wherein said drug comprises multi-
20 vitamins and combinations.
48. The coated drug of Claim 12 which said drug comprises an analgesic and one or more of an antihistamine, decongestant, antitussive or expectorant or a mixture thereof.
- 25 49. The coated drug of Claim 12 wherein said drug comprises celecoxib.
50. The coated drug of Claim 12 wherein said drug comprises oxaprozin.
51. The coated drug of Claim 12 wherein said drug comprises sildenafil
30 citrate.

52. The coated drug of Claim 12 wherein said drug comprises alendronate sodium.

53. A process for preparing a tablet coated with a gum selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum, and mixtures thereof which comprises:

(a) mixing said gum selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum and mixture thereof, with water and sufficiently dissolving said gum(s) in water, to prepare an aqueous gum coating composition useful for coating tablets receptive to such coating; and

(b) applying said aqueous coating composition in an adherent fashion to said tablet(s) whereby said coated tablet is formed and (optionally) drying said tablet(s) to form said coated tablet(s).

54. The process of Claim 53 wherein said aqueous coating composition is applied one or more times to a tablet to be coated and wherein the concentration of said gum(s) in said aqueous coating composition may be the same or different from application to application to said tablet.

55. The process of Claims 53-54 wherein said hydrocolloid comprises carrageenan gum.

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56. The process of Claims 53-54 wherein said hydrocolloid comprises guar.

57. The process of Claims 53-54 wherein said hydrocolloid comprises locust bean gum.

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58. The process of Claims 53-54 wherein said hydrocolloid comprises a mixture, blend or combination of hydrocolloids.

59. A gum suitable for forming a coating on a tablet receptive to said
5 coating, wherein said gum comprises a gum selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan and mixtures thereof in an amount in the range from about 0.05% to about 4% of the total gum coated tablet weight.

10 60. The gum of Claim 59 wherein said amount is in the range from about 0.1 to about 2% of the total gum coated tablet weight.

61. The gum of Claim 60 wherein said amount is in the range from about
15 0.5% to about 1.5% by weight.

62. The gum of Claim 59 wherein said tablet comprises aspirin.

63. The gum of Claim 59 wherein said tablet comprises ibuprofen.

20 64. The gum of Claim 59 wherein said tablet comprises acetaminophen.

65. The gum of Claim 59 wherein said tablet comprises naproxen sodium.

25 66. The gum of Claim 59 wherein said tablet comprises aspirin with caffeine.

67. The gum of Claim 59 wherein said tablet comprises buffered aspirin.

30 68. The gum of Claim 59 wherein said tablet comprises multi-vitamins and combinations.

69. The gum of Claim 59 wherein said drug comprises celecoxib.
70. The gum of Claim 59 wherein said drug comprises oxaprozin.
- 5 71. The gum of Claim 59 wherein said drug comprises sildenafil citrate.
72. The gum of Claim 59 wherein said drug comprises alendronate sodium.
- 10 73. The gum of Claim 59 wherein said tablet comprises an analgesic and one or more of an antihistamine, decongestant, antitussive, or expectorant or a mixture(s) thereof.
- 15 74. An active drug coated with a hydrocolloid coating prepared by the process of Claims 50-51.
75. The active drug of Claim 74 wherein said active drug comprises aspirin.
- 20 76. The active drug of Claim 74 wherein said active drug comprises ibuprofen.
77. The active drug of Claim 74 wherein said active drug comprises acetaminophen.
- 25 78. The active drug of Claim 74 wherein said active drug comprises sodium naproxen.
79. The active drug of Claim 74 wherein said active drug comprises aspirin with caffeine.
- 30

80. The active drug of Claim 74 wherein said active drug comprises buffered aspirin.

81. The active drug of Claim 74 wherein said active drug comprises multi-
5 vitamins and combinations.

82. The active drug of Claim 74 which said drug comprises an analgesic and one or more of an anti-histamine, decongestant, antitussive or expectorant.

10 83. The active drug of Claim 74 wherein said drug comprises celecoxib.

84. The active drug of Claim 74 wherein said drug comprises oxaprozin.

85. The active drug of Claim 74 wherein said drug comprises sildenafil
15 citrate.

86. The active drug of Claim 74 wherein said drug comprises alendronate sodium.

20 87. A method of treating a human patient (or animal) with a drug which comprises administering to said patient a therapeutically effective amount of an active drug(s) in a coated tablet(s), wherein said coated tablet(s) is coated with a hydrocolloid selected from the group consisting of locust bean gum (Galactomannans), guar gum, carrageenan gum and mixtures thereof and wherein said
25 tablet further comprises a therapeutically effective amount of a therapeutically effective drug in an amount beneficial to said patient or said animal.

88. The method of Claim 87 wherein said tablet is coated with guar gum.

30 89. The method of Claim 87 wherein said tablet is coated with locust bean gum.

90. The method of Claim 87 wherein said tablet is coated with carrageenan gum.
- 5 91. The method of Claim 87 wherein said hydrocolloid comprises a mixture, blend or combination of hydrocolloid(s).
92. The method of Claim 87 wherein said tablet comprises aspirin.
- 10 93. The method of Claim 87 wherein said tablet comprises ibuprofen.
94. The method of Claim 87 wherein said tablet comprises acetaminophen.
95. The method of Claim 87 wherein said tablet comprises naproxen
15 sodium.
96. The method of Claim 87 wherein said tablet comprises aspirin with caffeine.
- 20 97. The method of Claim 87 wherein said tablet comprises buffered aspirin.
98. The method of Claim 87 wherein said tablet comprises multi-vitamins and combinations.
25
99. The method of Claim 89 wherein said tablet comprises celecoxib.
100. The method of Claim 89 wherein said tablet comprises oxaprozin.
- 30 101. The method of Claim 89 wherein said tablet comprises sildenafil citrate.

102. The method of Claim 89 wherein said tablet comprises alendronate sodium.

5 103. The method of Claim 89 which said tablet comprises an analgesic and one or more of an antihistamine, decongestant, antitussive or expectorant or a mixture thereof.

104. The method of Claim 89 wherein said tablet comprises aspirin.

10 105. The method of Claim 89 wherein said tablet comprises ibuprofen.

106. The method of Claim 89 wherein said tablet comprises acetaminophen.

15 107. The method of Claim 89 wherein said tablet comprises naproxen sodium.

108. The method of Claim 89 wherein said tablet comprises aspirin with caffeine.

20 109. The method of Claim 89 wherein said tablet comprises buffered aspirin.

25 110. The method of Claim 89 wherein said tablet comprises multi-vitamins and combinations.

111. The method of Claim 89 which said tablet comprises an analgesic and one or more of an antihistamine, decongestant, antitussive or expectorant.

30 112. The method of Claim 90 wherein said tablet comprises aspirin.

113. The method of Claim 90 wherein said tablet comprises ibuprofen.

114. The method of Claim 90 wherein said tablet comprises acetaminophen.
115. The method of Claim 90 wherein said tablet comprises sodium
5 naproxen.
116. The method of Claim 90 wherein said tablet comprises aspirin with
caffeine.
- 10 117. The method of Claim 90 wherein said tablet comprises buffered
aspirin.
118. The method of Claim 90 wherein said tablet comprises multi-vitamins
and combinations.
- 15 119. The method of Claim 90 which said tablet comprises an analgesic and
one or more of an antihistamine, decongestant, antitussive or expectorant or a mixture
thereof.
- 20 120. The method of Claim 90 which said tablet comprises celecoxib.
121. The method of Claim 90 which said tablet comprises oxaprozin.
122. The method of Claim 90 which said tablet comprises sildenafil citrate.
- 25 123. The method of Claim 90 which said tablet comprises alendronate
sodium.
124. An article of manufacture comprising a tablet coated with a
30 composition comprising a hydrocolloid selected from the group consisting of locust
bean gum (galactomannans), guar gum, carrageenan gum, and mixtures thereof.

125. The article of Claim 124 wherein said coating composition comprises locust bean gum.

5 126. The article of Claim 124 wherein said coating composition comprises guar gum.

127. The article of Claim 124 wherein said coating composition comprises carrageenan gum.

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128. The article of Claim 124 wherein said composition comprises a mixture, blend or combination of hydrocolloids selected from the group consisting of locust bean gum (Galactomannans), guar gum and carrageenan gum.

15 129. The article of Claims 124-128 wherein said tablet contains an active ingredient selected from the group consisting of aspirin, ibuprofen, acetaminophen, naproxen sodium, aspirin with caffeine, buffered aspirin, celecoxib, oxaprozin, sildenafil citrate, aldenafil sodium, multi-vitamins and combinations thereof.

20 130. The article of Claim 129 wherein said active comprises aspirin.

131. The article of Claim 129 wherein said active comprises ibuprofen.

132. The article of Claim 129 wherein said active comprises
25 acetaminophen.

133. The article of Claim 129 wherein said active comprises naproxen sodium.

30 134. The article of Claim 129 wherein said active comprises aspirin with caffeine.

135. The article of Claim 129 wherein said active comprises buffered aspirin.

5 136. The article of Claim 129 wherein said active comprises multivitamins and combinations.

137. The tablet coating of Claim 1 wherein said active is selected from celecoxib, oxaprozin, sildenafil citrate, and aldenafil sodium.

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138. The coated drug of Claim 9 wherein said drug is selected from celecoxib, oxaprozin, sildenafil citrate, and aldenafil sodium.

139. The process of Claims 50 or 51 wherein said celecoxib, oxaprozin,
15 sildenafil citrate, and aldenafil sodium.

140. The tablet of claim 28 wherein said tablet is selected from celecoxib, oxaprozin, sildenafil citrate, and aldenafil sodium.

20 141. The method of claim 87 wherein said tablet is selected from celecoxib, oxaprozin, sildenafil citrate, and aldenafil sodium.

142. The article of claim 124 wherein said tablet is selected from celecoxib, oxaprozin, sildenafil citrate, and aldenafil sodium.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/28001

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 5 422 121 A (LEHMANN KLAUS ET AL) 6 June 1995 (1995-06-06)</p> <p>column 2, line 20 - line 46 column 2, line 66 - column 3, line 10 column 5, line 12 - line 36 column 5, line 49 - column 6, line 4 column 6, line 29 - line 36; claims 1,2; examples 3-6,9</p> <p style="text-align: center;">--- -/--</p>	<p>1,3-5,9, 11-13, 17,29, 41,46, 53,54, 56-58, 74,75, 87-89, 91,92, 104, 124-126, 128-130</p>

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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A document member of the same patent family

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/28001

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 652 313 A (DEN BOER PATRICK ET AL) 24 March 1987 (1987-03-24) column 1, line 5 - line 11 , sentence 46 - sentence 49 column 3, line 10 - line 20; claims 1-3 ---	1-3, 5-11, 53-56, 58,59, 124, 126-128
P,X	EP 0 974 344 A (SAMYANG CORP) 26 January 2000 (2000-01-26) page 4, paragraph 24 page 4, paragraph 27 - paragraph 29 page 4, paragraph 34 page 5, paragraph 43 -page 6, paragraph 44 page 6, paragraph 52 page 7; example 1; table 1 page 8; example 3; table 3 claims 1,2,6,7,14,17; examples 7,8 --- -/--	1,3-9, 11-13, 18,30, 42,53, 54, 56-61, 63,74, 76, 87-89, 91,93, 105, 124-126, 128,129, 131

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/28001

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	<p>WO 00 45794 A (FMC CORP) 10 August 2000 (2000-08-10)</p> <p>page 1, paragraph 1 page 4, last paragraph page 5, last paragraph -page 6, paragraph 2 page 7, line 24 - line 28 page 11, line 14 - line 27 page 12, line 13 - line 22 page 13, line 3 - line 10 page 13, line 24 - line 29; claims 1,2,6-14,24-34,38-40; examples 1-4,8,11,13,26</p>	<p>1,2, 5-10, 13-19, 29-31, 53-55, 58-64, 74-77, 87, 90-94, 112-114, 124, 127-132</p>
X	<p>DATABASE WPI Section Ch, Week 198726 Derwent Publications Ltd., London, GB; Class B07, AN 1987-181872 XP002159536 & JP 62 111917 A (SATO SEIYAKU KK), 22 May 1987 (1987-05-22) abstract</p>	<p>1,2,6, 10, 14-16, 59-61, 124,127</p>
X	<p>US 5 096 714 A (KUHRITS ERIC H) 17 March 1992 (1992-03-17)</p> <p>column 1, line 14 - line 81 column 2, line 6 - line 18 column 4, line 63 -column 5, line 5; examples 1,2</p>	<p>9-11,13, 17,18, 23,29, 30,35</p>
X	<p>BAWEJA J M ET AL: "MODIFIED GUAR GUM AS FILM FORMER" PHARMAZIE,VEB VERLAG VOLK UND GESUNDHEIT. BERLIN,DD, vol. 54, no. 9, September 1999 (1999-09), pages 678-681, XP000851020 ISSN: 0031-7144</p> <p>page 678, right-hand column, paragraph 1 - paragraph 2 page 681, left-hand column, paragraph 3 - paragraph 4</p>	<p>1,3,6-9, 11, 13-16, 53,54, 56, 59-61, 74,124, 126</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/28001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5422121 A	06-06-1995	DE 9015551 U AT 119389 T DE 59104870 D DK 485840 T EP 0485840 A ES 2071889 T	12-03-1992 15-03-1995 13-04-1995 06-06-1995 20-05-1992 01-07-1995
US 4652313 A	24-03-1987	EP 0228485 A JP 2108272 C JP 8019348 B JP 62127356 A	15-07-1987 06-11-1996 28-02-1996 09-06-1987
EP 0974344 A	26-01-2000	AU 4062799 A WO 0004924 A	14-02-2000 03-02-2000
WO 0045794 A	10-08-2000	AU 2872800 A	25-08-2000
JP 62111917 A	22-05-1987	JP 6062400 B	17-08-1994
US 5096714 A	17-03-1992	US 4965252 A US 5023245 A CA 2030449 A US 5445826 A US 5292518 A AU 617822 B AU 3661689 A CA 1333997 A DE 68905096 D DE 68905096 T EP 0349235 A GB 2221390 A, B JP 2048531 A US 5466469 A US 5118510 A US 5641511 A	23-10-1990 11-06-1991 23-05-1991 29-08-1995 08-03-1994 05-12-1991 04-01-1990 17-01-1995 08-04-1993 17-06-1993 03-01-1990 07-02-1990 19-02-1990 14-11-1995 02-06-1992 24-06-1997